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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,863	06/27/2003	Ryoichi Hashida	3462.1003-000	8202

21005 7590 01/12/2005

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EXAMINER	
HOWARD, ZACHARY C	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,863	HASHIDA ET AL.	
	Examiner	Art Unit	
	Zachary C Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 31, drawn to a method of diagnosing an allergic disease by measuring the expression level of NOR-1 receptor protein or the expression level of a gene encoding a NOR-1 receptor in eosinophil cells of a test subject, classified in class 435, subclass 7.2 or 6.

II. Claim 4, drawn to an oligonucleotide of at least 15 nucleotides complementary to a sequence encoding a NOR-1 receptor protein or its complementary strand, classified in class 536, subclass 24.31.

III. Claim 5-10, 32 and 33, drawn to a method of screening for a compound that modulates the expression level of a polynucleotide, classified in class 435, subclass 6.

IV. Claims 11 and 12, drawn to a method of screening for a compound by measuring binding to the NOR-1 receptor, classified in class 435, subclass 7.2.

V. Claims 13-14, 19, 25, 30 and 38 drawn to a compound that modulates the expression level of the gene encoding the NOR-1 gene, classification dependent on compound structure.

VI. Claims 15-18, 26-29, 34-37, 39-46, 52 and 53, drawn to a ligand of the NOR-1 receptor that is a therapeutic agent for a disease or an apoptosis-inducing agent, classification dependent on compound structure.

VII. Claims 20-21, drawn to a transgenic animal, classified in class 800, subclass 13.

VIII. Claim 22-24 and 47-51, drawn to a method of inducing apoptosis of a cell, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide can be used in a method of diagnosing an allergic disease by measuring the expression level of a gene encoding the NOR-1 receptor protein but can also be used in a method of amplifying a DNA sample containing the NOR-1 gene by PCR, which is a materially different process.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, III, IV and VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of diagnosis of an allergic disease, which is not required by any of the other Inventions. Invention III requires search and consideration of screening for compounds that modulate expression of the NOR-1 gene, which is not required by any of the other Inventions. Invention IV requires search and consideration of screening for compounds that bind the NOR-1 receptor, which is not required by any of the other Inventions. Invention VIII requires search and consideration of induction of apoptosis, which is not required by any of the other Inventions.

Invention I is unrelated to each of inventions V, VI, and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is a method of diagnosis and Inventions V, VI, and VII are compounds or transgenic animals that are not used in the method of diagnosis of Invention I.

Invention II is unrelated to each of Inventions III-VIII. In the instant case Invention II is an oligonucleotide and Inventions III-VIII are all physically and functionally distinct chemical entities, or in the case of the transgenic animals an organism, that have

different structures, activities, and functions, or are methods that do not use the oligonucleotide of Invention II.

Invention III is related to Invention V in that the compounds of Invention V are a subset of compounds that used in the method of Invention III. In the instant case the method of screening of Invention III can also be practiced with other compounds that do not modulate NOR-1 gene expression.

Invention III is unrelated to each of Inventions VI and VII. In the instant case Invention III is a method of screening and Inventions VI and VII are compounds or transgenic animals that are not used in the method of screening of Invention I.

Invention IV is related to Invention VI in that the compounds of Invention VI are a subset of compounds that used in the method of Invention VI. In the instant case the method of screening of Invention IV can also be practiced with other compounds that do not bind NOR-1 receptor.

Invention IV is unrelated to each of Inventions V and VII. In the instant case Invention IV is a method of screening and Inventions V and VII are compounds or transgenic animals that are not used in the method of screening of Invention IV.

Inventions V, VI and VII are unrelated to each other. Each of the inventions consists of functionally distinct chemical entities, or in the case of the transgenic animals an organism, that have different structures, activities, and functions.

Inventions V and VII are unrelated to Invention VIII. Invention VIII is a method of inducing apoptosis that does not use the compounds or transgenic animals of Invention V or VII.

Inventions VI and VIII are related as product and process of use. In the instant case, the ligands of the NOR-1 receptor of Invention VI could also be used in a method of purifying the receptor, which is a materially different process.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LORRAINE SPECTOR
PRIMARY EXAMINER